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FOX, DAVID T

ART UNIT	PAPER NUMBER
1638	10

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/70,023	Ye et al
Examiner	**Group Art Unit**
FOX	1638

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☑ Responsive to communication(s) filed on 11/20/a.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☑ Claim(s) 1-53 is/are pending in the application.

Of the above claim(s) 7-12, 16, 20, 24, 28-53 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☑ Claim(s) 1-6, 13-15, 17-19, 21-23, 25-27 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☑ Notice of Reference(s) Cited, PTO-892

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Interview Summary, PTO-413

☐ Notice of Informal Patent Application, PTO-152

☐ Other _____

Office Action Summary

Applicant's election of Group I in Paper No. 9 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 13-15, 17-19, 21-23 and 25-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Dependent claims are included in all rejections.

Claims 1, 13, 17, 21 and 25 are indefinite in their recitation of "a protein according to SEQ ID NO:4" as it is unclear whether the entire sequence of SEQ ID NO:4 is intended, and whether "according to" means an exact correspondence. If intended, replacement of the phrase "according to" with --comprising-- would obviate this rejection.

Claims 2-3, 14-15, 18-19, 22-23 and 26-27 are indefinite in their recitation of "a nucleic acid sequence" as it is unclear whether a subsequence of the entire SEQ ID NO:1 (or a subsequence of the recited portion thereof comprising nucleotides 81-1024) is intended, or if the complete SEQ ID NO or complete portion of nucleotides 81-1024 is intended. If the latter were intended, replacement of "a" before "nucleic acid" with --the-- would obviate this rejection.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4-6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to any nucleic acid from any source that hybridizes under conditions of moderate stringency to either SEQ ID NO:1, 2 or 3 or any portion thereof, wherein "portion" is defined in the specification as at least 8 contiguous nucleotides, or any DNA from any source which has at least 70% identity thereto, or any DNA from any source encoding a protein having at least 80% homology to SEQ ID NO:4, wherein said encoded protein "participates in meiocyte formation". In contrast, the specification only provides guidance for the isolation and characterization of a single gene encoding a single protein which "participates in meiocyte formation", wherein said gene is the *SPOROCYTELESS* gene from *Arabidopsis thaliana* which comprises SEQ ID NO:1, with the coding sequence of nucleotides 81-1024, and which encodes SEQ ID NO:4. No guidance is presented for the identification or isolation of any protein with 80% homology to SEQ ID NO:4 which would retain the ability to participate in meiocyte formation, or for any of a multitude of nucleic acid sequence variants or portions from a multitude of sources which would encode such a protein. Furthermore, since SEQ ID NO:3 corresponds to the *Ds* transposon which was used to isolate the plant gene via transposon tagging, rather than corresponding to the isolated plant gene itself, a multitude of sequences which hybridize to SEQ

ID NO:3 would not encode a plant protein which "participates in meiocyte formation", and said multitude of sequences have not been described in any way by the instant specification.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." *University of California* v. *Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." *Id.*

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus as broadly claimed. Given the lack of written description of the claimed products, any method of using them would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention at the time of filing. See Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111).

See *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism. See also Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991), where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

Claims 4-6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to a nucleic acid from *Arabidopsis thaliana* which comprises the *SPOROCYTELESS* gene comprising SEQ ID NO:1 (including the coding sequence of nucleotides 81-1024) or which encodes SEQ ID NO:4, or nucleic acid sequences which encode the same SEQ ID NO:4 but vary from SEQ ID NO:1 due to the degeneracy of the genetic code, does not reasonably provide enablement for a multitude of nucleic acid sequence variants or fragments from a multitude of sources which encode a multitude of proteins "which participate in meiocyte formation". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn to any nucleic acid from any source that hybridizes under conditions of moderate stringency to either SEQ ID NO:1, 2 or 3 or any portion thereof, wherein

"portion" is defined in the specification as at least 8 contiguous nucleotides, or any DNA from any source which has at least 70% identity thereto, or any DNA from any source encoding a protein having at least 80% homology to SEQ ID NO:4, wherein said encoded protein "participates in meiocyte formation". In contrast, the specification only provides guidance for the isolation and characterization of a single homeotic gene encoding a single protein which comprises a MADS box domain and which "participates in meiocyte formation", wherein said gene is the *SPOROCYTELESS* gene from *Arabidopsis thaliana* which comprises SEQ ID NO:1, with the coding sequence of nucleotides 81-1024, and which encodes SEQ ID NO:4. No guidance is presented for the identification or isolation of any protein with 80% homology to SEQ ID NO:4 which would retain the ability to participate in meiocyte formation, or for any of a multitude of nucleic acid sequence variants or portions from a multitude of sources which would encode such a protein.

The isolation and evaluation of homeotic genes involved in the formation of reproductive organs in plants is unpredictable. Spielman et al teach that little is known about the production of meiocytes in flowering plants, and that *Arabidopsis* is unique among cruciferous plants in its ability to tolerate polyploid pollen grains (see, e.g., paragraph bridging pages 2645 and 2646; page 2655, column 2, third and fourth full paragraphs). See also the discussion of unpredictability in the immediately following enablement rejection.

Given the claim breadth, the lack of guidance in the specification, the lack of knowledge about meiocyte-involved genes, and the apparently exceptional nature of *Arabidopsis*, undue

experimentation would have been required by one skilled in the art to identify and evaluate a multitude of non-exemplified nucleic acids from a multitude of sources encoding a multitude of non-exemplified proteins which "participate in meiocyte formation".

Furthermore, since SEQ ID NO:3 corresponds to the *Ds* transposon which was used to isolate the plant gene via transposon tagging, rather than corresponding to the isolated plant gene itself, a multitude of sequences which hybridize to SEQ ID NO:3 would not encode a plant protein which "participates in meiocyte formation". Undue experimentation would have been required by one skilled in the art to obtain transposon recognition sites which "participate in meiocyte formation".

Claims 13-15, 17-19, 21-23 and 25-27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn to a multitude of transformed plant cells, plants and seeds of any species transformed with nucleic acids comprising SEQ ID NO:1 or its coding region or any sequence which encodes SEQ ID NO:4, wherein said nucleic acids may be used in a method to confer seedlessness or pollenlessness in plants transformed therewith. In contrast, the specification provides no guidance for the transformation of any plant species with SEQ ID NO:1, its coding region, or any nucleic acid which encodes the same protein, wherein male- or female-sterile plants are obtained.

Plant transformation with homeotic genes is unpredictable. Matsuoka et al teach that plant transformation with a homeotic gene encoding a protein which confers sterility also confers the deleterious phenotypes of severe dwarfing and stunting, and severe reduction in leaf area, which would deprive the plant of sustantial amounts of carbohydrates produced during photosynthesis (see, e.g., page 1039, Abstract; page 1042).

Furthermore, the instant *SPOROCYTELESS* gene has not been conclusively demonstrated to function to initiate meiocyte formation, and it is unclear whether its ectopic expression or inhibition would affect or interfere with meiocyte formation. Schiefthaler et al teach the *Arabidopsis NOZZLE* gene, which they admit is synonymous with the *SPOROCYTLESS* gene (see, e.g., page 11669, column 1, "Note Added in Proof"; see also appended Sequence Search results which demonstrate that the coding regions of the cDNA of SEQ ID NO:1 correspond exactly to the coding regions of the genomic clone of Figure 2 of the reference on page 11667). However, Schiefthaler et al teach that the gene was transcribed in non-floral organs, even though no phenotype was observed (see, e.g., page 11667, column 2, second full paragraph).

Given the claim breadth, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to evaluate and obtain any change in phenotype, including pollenlessness or seedlessness in the absence of other effects deleterious to whole plant health, in plants transformed with the exemplified or non-exemplified nucleic acids.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6 are rejected under 35 U.S.C. 102(a) as being anticipated by Reichert et al (Accession No. O81836, submitted June 1998).

The claims are broadly drawn to any isolated nucleic acid which encodes SEQ ID NO:4, or any variant of SEQ ID NO:1 due to the degeneracy of the genetic code, or any nucleic acid sequence variant with at least 70% identity to SEQ ID NO:1 or which encodes a protein with at least 80% identity to SEQ ID NO:4.

Reichert et al teach an isolated nucleic acid ("SEQUENCE FROM N.A.") which encodes a protein with 99.6% overall identity to SEQ ID NO:4, wherein the single amino acid difference could have been due to a sequencing or printing error (see enclosed Sequence Search report).

Claims 2-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Rounsley et al (Accession No. B98482 submitted 1997).

The claims are broadly drawn to isolated nucleic acid sequences comprising any nucleotide sequence found in SEQ ID NO:1, or any "portion" of SEQ ID NO:1 of at least 8 nucleotides, wherein said sequence or portion thereof has at least 70% identity to SEQ ID NO:1 or

nucleotides 81-1024 thereof. Rounsley et al teach an isolated nucleic acid with 228 contiguous nucleotides of SEQ ID NO:1, from nucleotide 529 through 757, and 152 contiguous nucleotides from of SEQ ID NO:1, from nucleotide 789 through 941, wherein said nucleic acid sequence taught by the reference has 82.1% local similarity with SEQ ID NO:1 (see enclosed Sequence Search).

Claims 4-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Weigel et al.

The claims are broadly drawn to isolated nucleic acid sequences comprising any nucleotide sequence found in SEQ ID NO:1, or any "portion" of SEQ ID NO:1 of at least 8 nucleotides, wherein said sequence or portion thereof has at least 70% identity to SEQ ID NO:1 or nucleotides 81-1024 thereof, or any sequence which hybridizes to said sequence or 8 nucleotide portion under moderately stringent conditions, wherein said nucleic acid sequences encode a protein which participates in meiocyte formation, defined in the specification as sporogenesis which occurs in flowers, and exemplified by a MADS box-containing protein.

Weigel et al teach the isolated *LEAFY* gene which would inherently comprise at least one nucleotide of SEQ ID NO:1 or would hybridize to any 8 nucleotide portion of SEQ ID NO:1 under moderately stringent conditions, wherein said *LEAFY* gene enocdes a MADS box-containing protein which participates in meiocyte formation, as evidenced by the requirement of *LEAFY* gene product for the initiation of flowers in which meiocyte formation occurs, and as evidenced by the failure of mutant plants lacking a functional *LEAFY* gene to produce anthers, in

which the production of male meiocytes occur (see, e.g., page 843, Abstract and penultimate paragraph of column 2; paragraph bridging pages 843 and 844; page 844, column 2).

Claims 4-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Pnueli et al.

Pnueli et al teach the isolated *TAG1* gene which would inherently comprise at least one nucleotide of SEQ ID NO:1 or would hybridize to any 8 nucleotide portion of SEQ ID NO:1 under moderately stringent conditions, and which encodes a MADS box-containing protein which participates in meiocyte formation, since its inactivation in transgenic plants results in the abolition of stamens in which the formation of male meiocytes occurs (see, e.g., page 163, Abstract; page 164, paragraph bridging the columns and first full paragraph of column 2; page 165, column 2).

Claims 13-15, 17-19, 21-23 and 25-27 are deemed free of the prior art, given the failure of the prior art to teach or suggest plant transformation with isolated nucleic acids comprising SEQ ID NO:1, or their coding regions, or with isolated nucleic acids encoding SEQ ID NO:4, for the obtention of seedless or pollenless plants or any other phenotypic change.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (703) 308-0280. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (703) 306-3218. The fax phone number for this Group is (703) 872-9306. The after final fax phone number is (703) 872-9307.

February 9, 2003

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1638